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10 **UNITED STATES DISTRICT COURT**
11 **EASTERN DISTRICT OF WASHINGTON**

12 STATE OF WASHINGTON, et al.,

13 Plaintiffs,

14 v.

15 UNITED STATES FOOD AND
DRUG ADMINISTRATION, et al.,

16 Defendants.
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NO. 1:23-cv-03026-TOR

PLAINTIFF STATES' RESPONSE
TO MOTION TO INTERVENE

I. INTRODUCTION

Seven states with restrictive abortion laws and policies—Idaho, Iowa, Montana, Nebraska, South Carolina, Texas, and Utah (the “Proposed Intervenor”)—seek to intervene in this action addressing FDA’s regulation of mifepristone, in spite of the abundant evidence of the drug’s safety and efficacy. But the Proposed Intervenor’s asserted interest in enforcing their own state laws is entirely divorced from the claims and issues raised in this lawsuit. Instead, as the Proposed Intervenor candidly admit in their Motion to Expedite (ECF No. 90), their interest is in appealing an order this Court has already issued, on a motion in which they did not seek to participate.

That falls far short of the requirements of Rule 24. The Proposed Intervenor has no protectable interest here, because this challenge to federal agency action will not affect the Proposed Intervenor’s laws or ability to regulate abortion within their borders. Nor is it necessary or appropriate to expand the scope of this lawsuit to include their claims seeking to restore a previous FDA restriction on mifepristone that is not the subject of this case, but is already the subject of separate litigation elsewhere. The sparse and conclusory Motion to Intervene fails to establish any of the factors warranting either mandatory or permissive intervention. The Motion should be denied.

II. ARGUMENT

A. There Is No Right to Mandatory Intervention

The Proposed Intervenor do not meet their burden of demonstrating any

1 of the four mandatory intervention factors. *Cooper v. Newsom*, 13 F.4th 857,
 2 864–65 (9th Cir. 2021). “Failure to satisfy any one of the requirements is
 3 fatal” *Perry v. Proposition 8 Official Proponents*, 587 F.3d 947, 950 (9th
 4 Cir. 2009).

5
 6 **1. The Proposed Intervenors do not have a significantly protectable interest in the claims at issue in this litigation**

7 As a threshold matter, the Proposed Intervenors’ assertion that “practical
 8 considerations” drive the “significantly protectable interest” analysis and broadly
 9 favor intervention, ECF No. 76 at 2, 4–5, is incorrect. The Ninth Circuit recently
 10 held that, notwithstanding its prior “liberal policy in favor of intervention,” if the
 11 two “core,” “irreducible” elements of Rule 24(a)(2)’s “significantly protectable
 12 interest” analysis are not satisfied, “a putative intervenor lacks *any* interest under
 13 Rule 24(a)(2), *full stop*.” *Cal. Dep’t of Toxic Substances Control v. Jim Dobbas,*
 14 *Inc.*, 54 F.4th 1078, 1088 (9th Cir. 2022) (emphasis added). The Proposed
 15 Intervenors cannot satisfy this standard.

16 At its “irreducible minimum,” those two core elements are that: (1) “the
 17 asserted interest be protectable under some law,” and (2) “there exists a
 18 relationship between the legally protected interest and the claims at issue.” *Id.* at
 19 1088 (cleaned up). Seeking to pursue a similar claim to the existing lawsuit is not
 20 enough; a putative intervenor must establish that resolution of the lawsuit
 21 “actually will affect” its legally protected interest. *Donnelly v. Glickman*, 159
 22 F.3d 405, 409–11 (9th Cir. 1998). In *Donnelly*, intervention was denied where

1 female plaintiffs raised sex discrimination claims and the putative intervenors
 2 sought to raise similar claims against the same employer on behalf of men. *Id.*
 3 The court held that the male employees’ claims were “unrelated” to the plaintiffs’
 4 “*particular* claims of ‘hostile-work-environment’ discrimination” because none
 5 of the plaintiffs’ remedies—aimed at ending harassment of women—would
 6 directly or necessarily affect the putative intervenors’ claimed interest in
 7 preventing discrimination against men. *Id.*

8 The same is true here. The Proposed Intervenors’ claims solely concern
 9 FDA’s elimination of a prior in-person dispensing requirement. But this lawsuit
 10 challenges different REMS restrictions (*i.e.*, the patient agreement form, provider
 11 certification, and pharmacy certification). *See* ECF No. 35 ¶¶ 1–8. The in-person
 12 dispensing requirement is not at issue in this case and will neither be eliminated
 13 nor reinstated as a result of this suit. For this reason alone, intervention should be
 14 denied. *Donnelly*, 159 F.3d at 409–10 (for intervention, “[i]t is not enough that
 15 both groups assert [similar] claims against the same defendants”); *Ctr. for*
 16 *Biological Diversity v. Lubchenco*, No. 09-04087 EDL, 2010 WL 1038398, at *2
 17 (N.D. Cal. Mar. 19, 2010) (denying intervention where Alaska’s claimed interests
 18 in wildlife management were not “sufficiently related to” whether federal agency
 19 erred in not listing ribbon seal as endangered species).

20 The Proposed Intervenors’ invocation of their own state abortion laws and
 21 the “health and well-being” of their residents, ECF No. 76 at 4, does not alter this
 22 conclusion. First, their concerns about the “ability to enforce” their *more*

1 restrictive abortion laws are illogical. *Id.* The Plaintiff States do not challenge
 2 any of the Proposed Intervenor’s laws on abortion, which impose additional
 3 restrictions beyond FDA’s REMS. *See, e.g.*, ECF No. 76-1 ¶¶ 52, 73, 75; *see also*
 4 *infra* at 6. Accordingly, “resolution of this case would not impair those States’
 5 ability to enforce their own laws regulating mifepristone.” *See Am. College of*
 6 *Obstetricians & Gynecologists (ACOG) v. FDA*, 467 F. Supp. 3d 282, 286 (D.
 7 Md. 2020) (denying intervention to ten states in action challenging FDA’s in-
 8 person dispensing requirement).

9 Further, the Proposed Intervenor’s “have not submitted evidence to support
 10 their fears” of any harm to their residents based on the 2023 REMS, “other than
 11 [their] speculative beliefs.” *Standard Heating & Air Conditioning Co. v. City of*
 12 *Minneapolis*, 137 F.3d 567, 571 (8th Cir. 1998) (denying intervention because
 13 interests were too speculative to be “direct, substantial and legally protectable”);
 14 *see also United States v. Alisal Water Corp.*, 370 F.3d 915, 919 (9th Cir. 2004)
 15 (speculative interests insufficient to support a right to intervention); *Donnelly*,
 16 159 F.3d at 411. Moreover, a core premise of their assertion of harm is factually
 17 mistaken. They highlight the “23-year requirement” that mifepristone be
 18 “administered in person in a clinical setting.” ECF No. 76-1 ¶ 61. But since 2016,
 19 the REMS has allowed patients to take mifepristone “at a location of [their]
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 21
 22

1 choice.” *See ACOG*, 467 F. Supp. 3d at 285. The 2023 REMS did not alter this.¹

2 In any event, because “this case will not eliminate any state’s ability to
3 continue to regulate medication abortion,” the Proposed Intervenor’s “broader
4 policy interests . . . cannot serve as a basis for mandatory intervention.” *ACOG*,
5 467 F. Supp. 3d at 289.

6 **2. Disposition of this suit will not impair the Proposed Intervenor’s**
7 **regulation of abortion within their borders**

8 Because the Proposed Intervenor has failed to demonstrate a
9 significantly protectable interest in the claims at issue in this case, “there can be
10 no impairment of the ability to protect it.” *Am. Ass’n of People with Disabilities*
11 *v. Herrera*, 257 F.R.D. 236, 252 (D.N.M. 2008); *see also United States v.*
12 *Arizona*, 2010 WL 11470582, at *3 (D. Ariz. Oct. 28, 2010). But even if they had
13 such an interest, they still fail to establish impairment.

14 Fundamentally, the claims in this lawsuit are factually and legally distinct
15 from the claims the Proposed Intervenor seeks to assert against removal of the
16 in-person dispensing requirement. And even if they could show this case might
17 *affect* their interests, they cannot prove *impairment* because they have “other
18 means by which [they] may protect” those interests. *Alisal Water Corp.*, 370 F.3d
19 at 921. As discussed above, a ruling in this case does not affect the Proposed

20 ¹ For these same reasons, Proposed Intervenor lacks standing. *Jim Dobbas*,
21 54 F.4th at 1085 (intervenor seeking relief “that is broader than or different from
22 the relief sought by existing parties” must “possess constitutional standing”).

Intervenors’ abilities to regulate abortion within their borders. *Supra* at 4. Just as in *ACOG*, “Plaintiffs do not seek the invalidation of the States’ abortion laws.” *ACOG*, 467 F. Supp. 3d at 289. Notably, many of the Proposed Intervenors have already imposed their own state-law restrictions on medication abortion, including REMS-like requirements. *See, e.g.*, Neb. Rev. Stat. § 28-335(2) (requiring physicians to be physically present during medication abortions); Utah Code 76-7-302(4) (“An abortion may be performed only in an abortion clinic or a hospital”); Idaho Code § 18-622 (banning abortions except in extremely limited circumstances); Tex. Health & Safety Code §§ 245.002, 170A.002 (criminalizing the provision of nearly all abortions, including medication abortion). This lawsuit requests no relief related to those state laws.

Further, the Proposed Intervenors can assert their purported interests via their own lawsuit, rather than seeking to commandeer this one. *See United States v. City of Los Angeles*, 288 F.3d 391, 402 (9th Cir. 2002) (denying intervention where it was “doubtful” that police reform advocates’ “interests are impaired by” order relating to LAPD constitutional violations because “[t]he litigation does not prevent any individual from initiating suit against LAPD officers who engage in unconstitutional practices”); *Mi Pueblo San Jose, Inc. v. City of Oakland*, C06-4094VRW, 2007 WL 578987, at *7 (N.D. Cal. Feb. 21, 2007) (“[I]ntervention is also improper because alternative forums exist for Asociacion to vindicate its asserted interests.”); *California v. Health & Hum. Servs.*, 330 F.R.D. 248, 254 (N.D. Cal. 2019) (“[T]his action will not impede or impair [Oregon’s] ability to

1 protect [its] interests, because Oregon could adequately protect those interests by
 2 filing a separate suit”). Indeed, a separate lawsuit addressing the in-person
 3 dispensing requirement’s legality is being actively litigated in Texas. Compl., *All.*
 4 *for Hippocratic Med. v. FDA*, No. 2:22-cv-00223-Z (N.D. Tex.), ECF No. 1 ¶
 5 394. For this reason, the Proposed Intervenor’s reliance on *California ex rel.*
 6 *Lockyer v. United States*, 450 F.3d 436, 443 (9th Cir. 2006), is misplaced because
 7 there, the court determined the proposed intervenors would have been barred
 8 from bringing “a separate suit where they could argue” their position. By contrast,
 9 because the Proposed Intervenor has other ways to pursue their legal interests
 10 (including seeking intervention in the Texas litigation), they cannot show that
 11 this case will impair any significant protectable interest.²

12 **3. If the Proposed Intervenor has a protectable interest in this**
 13 **suit, FDA can adequately represent it**

14 The Proposed Intervenor has failed to demonstrate that FDA does not
 15 adequately represent their interests as they pertain to this lawsuit. As made clear
 16 by the proposed complaint (ECF No. 76-1), their claims solely concern FDA’s
 17 elimination of the in-person dispensing requirement, not the restrictions
 18 challenged by the Plaintiff States. Of course, any nonparty can assert that existing
 19 parties will not raise and prosecute new claims on its behalf—but that is not the

20 ² Proposed Intervenor has asserted no protectable interest that could be
 21 impaired by this Court’s preliminary injunction, which in any event is limited by
 22 its terms to the Plaintiff States and does not apply to Proposed Intervenor.

1 purpose of Rule 24. *See Piedmont Paper Prods., Inc. v. Am. Fin. Corp.*, 89 F.R.D.
 2 41, 43–44 (S.D. Ohio 1980) (denying intervention because, although no
 3 “defendants have any interest in asserting the counterclaims advanced by the
 4 applicant . . . [w]ith regard to defense of *this action*, the applicant seeks relief
 5 identical to that requested by the current defendants”) (emphasis added).

6 Moreover, even if the Proposed Intervenors asserted an interest that could
 7 be impaired by the current litigation, FDA adequately represents it. FDA has
 8 every incentive and ability to defend its own decision on the REMS requirements
 9 challenged here, and indeed is vigorously doing so. *See* ECF No. 51 (FDA Opp’n
 10 to Mot. for Prelim. Injun.); *see, e.g., Cedars-Sinai Med. Ctr. v. Shalala*, 125 F.3d
 11 765, 768 (9th Cir. 1997); *Am. Fed’n of State, Cty. & Mun. Emps. Council 79 v.*
 12 *Scott*, 278 F.R.D. 664, 670 (S.D. Fla. 2011) (“The [proposed intervenor’s]
 13 interests . . . are impaired only if the [Executive Order] is ruled unconstitutional.
 14 However, the [defendant] Governor . . . has every reason to defend this policy.”).
 15 For this reason too, mandatory intervention is inappropriate.

16 **4. The Motion to Intervene is untimely**

17 Finally, the Proposed Intervenors’ motion is untimely under the
 18 circumstances. *See Alisal Water Corp.*, 370 F.3d at 921 (“Timeliness is a flexible
 19 concept; its determination is left to the district court’s discretion.”); *League of*
 20 *United Latin Am. Citizens v. Wilson*, 131 F.3d 1297, 1303 (9th Cir. 1997) (“[T]he
 21 timeliness inquiry demands a more nuanced, pragmatic approach.”). In particular,
 22 they seek expedited consideration based on the deadline for appealing this

1 Court’s preliminary injunction—an injunction that does not affect any legitimate
 2 interest of the Proposed Intervenors, as it is expressly limited to the eighteen
 3 Plaintiff States. ECF No. 90 at 2; Beneski Decl. Ex. A (confirming that Proposed
 4 Intervenors seek to be “included with respect to any appeal rights that may run
 5 from the court’s grant of preliminary relief”). And yet, they did not move to
 6 intervene until *after* the preliminary injunction was fully briefed and argued.

7 **B. Permissive Intervention Should Be Denied**

8 Permissive intervention is “not intended to allow the creation of whole new
 9 lawsuits by the intervenors.” *S. Cal. Edison Co. v. Lynch*, 307 F.3d 794, 804 (9th
 10 Cir. 2002), *modified*, 307 F.3d 943 (9th Cir. 2002) (cleaned up). Because
 11 intervention will vastly complicate this case without any benefit, this Court
 12 should reject the Proposed Intervenors’ bid for permissive intervention as well.

13 First, there is no “common question of law or fact” between the existing
 14 lawsuit and the elimination of the in-person dispensing requirement such that
 15 intervention under Rule 24(b)(1)(B) is warranted. Although the Proposed
 16 Intervenors assert their claims are “grounded in the same facts and the same laws”
 17 as the Plaintiff States’, ECF No. 76 at 7, permissive intervention is not an
 18 appropriate vehicle to bring tangentially related claims that would “unnecessarily
 19 expand[] the lawsuit” beyond its original scope. *Van Hoomissen v. Xerox Corp.*,
 20 497 F.2d 180, 182 (9th Cir. 1974) (denying EEOC intervention to bring claims
 21 alleging discriminatory hiring practices in a retaliation lawsuit); *see also Cooper*,
 22 13 F.4th at 868 (denying intervention by district attorneys seeking to enforce

1 execution protocol where they did not draft the protocol and were not authorized
2 to defend its constitutionality, the issue in the “main action”).

3 Permitting the Proposed Intervenors to inject tangential claims will also
4 unduly delay and increase the complexity of this litigation. Fed. R. Civ. P.
5 24(b)(3); *Perry*, 587 F.3d at 955–56. As the *ACOG* court recognized, “permissive
6 intervention is [] not advisable because it would result in the injection of issues
7 relating to numerous different state laws into a case that . . . focuses squarely on
8 federal regulations.” 467 F. Supp. at 292 (“intervention would require the Court
9 to grapple with issues of the laws of ten different states”); *see* Dkt. 76-1 ¶¶ 55,
10 71, 80, 85, 90, 100 (alleging FDA’s elimination of the in-person dispensing
11 requirement upset reliance interests baked into their state laws). In short, this
12 Court should deny the Proposed Intervenors’ request that the Court manage two,
13 unrelated cases under one, unwieldy docket number. *See Stringfellow v.*
14 *Concerned Neighbors in Action*, 480 U.S. 370, 380, (1987) (“[A] . . . judge’s
15 decision on how best to balance the rights of the parties against the need to keep
16 the litigation from becoming unmanageable is entitled to great deference.”);
17 *Montgomery v. Rumsfeld*, 572 F.2d 250, 255 (9th Cir. 1978) (affirming denial of
18 permissive intervention that would “unnecessarily delay and complicate the
19 case”). Accordingly, permissive intervention should be denied.

20 III. CONCLUSION

21 For the foregoing reasons, the Plaintiff States respectfully request that the
22 Court deny Proposed Intervenors’ Motion to Intervene.

1 DATED this 13th day of April, 2023.

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CERTIFICATE OF SERVICE

I hereby certify that on April 13, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

DATED this 13th day of April, 2023, at Seattle, Washington.

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